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09/269,250	05/21/1999	ELSA AFRA, JULIA, MARIA GOULMY	2799/58994	9675

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/269,250	GOULMY, ELSA AFRA, JULIA, MARIA	
	Examiner	Art Unit	
	Jehanne Souaya Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-12 and 14-24* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☒ Claim(s) *2-4, 7-10, 14,and 23* is/are allowed.

6)☒ Claim(s) *5,6,11,12,15,20-22 and 24* is/are rejected.

7)☒ Claim(s) *12,15-17 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Currently, claims 2-12, and 14-24 are pending in the instant application. Claims 18 and 19 have been withdrawn from consideration as being drawn to a non elected invention. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Objections and Rejections

Claim Objections

3. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims fail the infringement test. See MPEP 608.01(n). The structure of the nucleic acids cannot be determined from the recitation of claims 2 or claim 3, and thus the nucleic acids of claim 15 can be separately infringed from the method of claim 3.

4. Claim 12, and consequently newly added claim 24, are objected to because the claims fail the infringement test because the probes can be separately infringed from the method of claim 2 (or 7).

5. Claims 16 and 17 are improperly dependent from claim 7 (or 2) because the methods do not stipulate a specific structure as in claims 16 and 17. The kits can be separately infringed from either the method of claim 7 or 2.

6. The amendments to claims 12 and 15-17 have not overcome these objections. Appropriate correction is required. For example, amending these claims to independent form, and thus not dependent on method claims, would overcome these objections.

Claim Rejections - 35 USC § 112

7. Claims 11-12, 15, and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acid sequences for genomic typing of alleles of the Minor Histocompatibility antigen HA-1. Such claims are either not drawn to any specific sequence (ie: claim 12) or recite language such as "specifically binding to... under stringent conditions", "90% homologous to...", "a fragment of about 5-50 nucleotides used as a probe for HA-1 typing" (claims 11, 15, and 20-22). Such claims encompass a large genus of sequences with substantial nucleotide variability including sequences outside the regions described in the

specification such that the partial sequence of intron a (SEQ ID NO: 1, SEQ ID NO: 21, and SEQ ID NO: 22), exon a and exon b do not represent a substantial portion of the genus of sequences encompassed by the claims.

With regard to claims 11, 12, and 15 the specification does not provide sufficient written description as to the sequence of the HA-1 antigen, or the cDNA or genomic DNA that encodes the full HA-1 antigen. The specification teaches allele typing of the HA-1 peptide, which is disclosed as SEQ ID NO 17. Two alleles are present resulting from a sequence change at nucleotide position 8 of SEQ ID NO 17 (nucleic acid sequence that encodes the HA-1 peptide), the "R" allele (SEQ ID NO 17) and the "H" allele (SEQ ID NO 19) corresponding to an Arginine or a Histidine at the 3rd position of the HA-1 nonapeptide (VLXDDLLEA, where X is either arginine or histidine). The specification teaches that typing these two alleles is important in typing potential donors for bone marrow transplants to prevent Graft versus Host Disease (GVHD), as patients, from two families, receiving bone marrow transplants from HLA identical donors within the family were found to develop GVHD. The specification teaches that allele typing of the HA-1 nonapeptide showed that donors and recipients differed in the HA-1 allele (p 21, example 1). The specification teaches the skilled artisan how to type the "H" or the "R" allele in a subject using the probes and primers disclosed, as well as the partial exon a and exon b sequences shown in figure 11, and the partial intron a sequence of SEQ ID NO 1. The specification teaches the sequence of the HA-1 peptide (SEQ ID NO 17 or 19) (see figure 5, p. 5-6). However, the claimed products, and kits, encompass using genomic and cDNA sequences that have not been taught or described in the specification. The specification teaches that the HA-1 peptide is encoded by 2 exons from the KIAA0223 gene (p 6 and 7), and teaches a partial

sequence (p. 6) of the intron located between these two exons (SEQ ID NO 1). The specification, however does not teach the full sequence of the HA-1 antigen, nor does the specification teach the cDNA or genomic DNA that corresponds to the nucleic acid sequences that encode the antigen. The specification teaches that the KIAA0223 gene encodes the HA-1 antigen, but does not disclose what sequences within the KIAA0223 gene correspond to the HA-1 gene. It cannot be determined from the disclosure in the specification if the gene product of the KIAA0223 gene is the HA-1 antigen, wherein the HA-1 peptide is a peptide located within the HA-1 antigen (The specification does not teach that the KIAA0223 gene is the HA-1 gene) or whether the complete sequence of the HA-1 antigen is the HA-1 nonapeptide (SEQ ID NOS 17 or 19) as the specification states that The GvHD associated mH antigen HA-1 is a nonapeptide derived from the di allelic KIAA0223 gene (p. 21). As the claims are drawn to nucleic acids for typing derived from only partially disclosed sequences, and the specification does not adequately describe these sequences, such claims do not meet the written description requirement of 112, first paragraph.

With regard to all the rejected claims, and more specifically, with regard to the recitation of "specifically binding… under stringent conditions", the specification does define the term 'specifically binding". The specification defines "specific hybridization" of a primer to a target region to mean that during the amplification step, the primer forms a duplex with part of the region or with the entire region under the experimental conditions used and that under those conditions said primer does not form a duplex with other regions of the polynucleic acids in the sample. Firstly it is noted however, that the conditions set forth in the claims are "stringent conditions" and that such conditions can encompass low, medium or high stringency.

Depending on how stringent the conditions are, mismatch between probe and target would be possible, thus allowing for hybridization to occur to other polynucleic acids. Further, the "sample" in the specification is not defined, such that a nucleic acid coming into contact with a sample only containing SEQ ID NO: 1, would not limit the structure of the probe with regard to non specific hybridization in a sample containing other nucleic acid sequences. In addition, the specification has not taught or described which minimum number of sequences from either SEQ ID NO: 1, 17, or 19 would be required in a nucleic acid such that it would only specifically bind to SEQ ID NO: 1, 17, or 19, and no other possible nucleic acids in a sample. As such, apart from complete complements of SEQ ID NOS: 1, 17, or 19, under conditions of the highest stringency, no correlation has been made with regard to the structure of the encompassed nucleic acids and the ability to "specifically bind to SEQ ID NO: 1, 17 or 19". The same holds for claims reciting "90% homology" and "fragment of 5 to 50 nucleotides long... that can be used as a primer or a probe for HA-1 typing". The specification has not defined which sequences from either SEQ ID NO: 1, 17, or 19 would be required in a nucleic acid such that it could be used for HA-1 typing. As such, apart from complete complements of SEQ ID NOS: 1, 17, or 19, under conditions of the hightest stringency, no correlation has been made with regard to the structure of the encompassed nucleic acids and the ability to type HA-1. It should be noted also, that claims reciting the fragment language with the upper length limitation of 50 nucleotides encompass sequences that need only have a very limited number of sequences in common, and even none at all, with the recited SEQ ID NOS. For example, SEQ ID NO: 1 is 377 nucleotides long. A sequence that has 90% identity could be different in 37 contiguous positions than that of SEQ ID NO: 1. A fragment of such reads on any 50mer sequence. The same holds for fragments of SEQ

ID NOS 17 and 19. The claim appears to recite that the isolated nucleic acid is 5 to 50 nucleotides long, not that the fragment from the recited SEQ ID NO: is 5-50 nucleotides because such would not make sense with regard to SEQ ID NO: 17 and 19 which are only 27mers. Thus, a fragment only from SEQ ID NO: 17 could not be 50 nucleotides long, unless it included additional sequences.

With the exception of the disclosed SEQ ID NOS, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The response traverses the rejection. The response asserts that the examiner must realize that small nucleotide alterations can be made without significantly affecting the properties of the polynucleic acid and that if such were not protected by the claims, applicant would not be able to obtain fair protection. This argument has been thoroughly reviewed but was not found persuasive. The rejection set forth above is in keeping with the written description guidelines set forth by the office (see MPEP 2163). As the claims encompass a much larger genus of nucleic acids than have been described by the specification, the examiner is bound by those guidelines. For these reasons and the reasons already made of record, the rejection is maintained.

8. Claims 5, 6, 12 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the recitation of "said 3' primer" as it is unclear if the "primer" being referred to is the 3' primer designated in claim 4, or the 3' primer designated in claim 5 (it is noted that each of these 3' primers appear to be different).

Claim 6 lacks sufficient antecedent basis for the recitation of "the primers". Primers are not recited previously in claim 6. Further, it is noted that claim 6 is dependent on itself, recites a method, and only discloses products with no positive process steps.

The structure of the nucleic acids of claim 12 cannot be determined as the claim is drawn to products which are dependent on method claims that do not set forth any specific structure for the claimed products.

The response asserts that the claims have been amended to overcome these rejections. However, the amendments are not sufficient to overcome the rejections maintained above.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 12 is rejected under 35 U.S.C. 102(a) as being anticipated by Levi et al (Journal of the American Society for Horticultural Science; vol. 112, no:1, pp 74-78, abstract and sequence provided).

Levi et al teach a sequence (a 10 mer) that has 80% identity to SEQ ID NO 19. The intended use for the probe of claims 12 is given no patentable weight. Further, it is noted that such sequence possess enough identity to the disclosed SEQ ID NO 19 so as to be able to hybridize to the complement of SEQ ID NO 19 under stringent conditions (no specific conditions set forth).

The response asserts that the claims have been amended to distinguish over Levi. This argument is not found persuasive because claim 12 has not been amended.

11. Claims 12 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Noble et al (Drug Development Research, vol. 34, 1995, pp 184-195, abstract and sequence provided).

Noble teaches a sequence (a 12 mer) that possesses 83% identity to SEQ ID NO 17. The intended use for the product of claims12 is given no patentable weight. Further, it is noted that such sequences possess enough identity to the disclosed SEQ ID NO 17 so as to be able to hybridize to the complement of SEQ ID NO 17 (no specific conditions recited).

The response asserts that the claims have been amended to distinguish over Nobel. This argument is not found persuasive. As noted previously, claim 12 has not been amended. Further, the sequence of Nobel is a 12 mer and thus meets the length limitation of claim 21. SEQ ID NO: 17 is a 27 mer. A sequence possessing 90% identity can encompass at least 2 mismatches. Since the claim does not stipulate that such mismatches are not contiguous and does not limit the identity of the mismatches, the sequence of Nobel represents a 'fragment of about 5-50 nucleotides long' of a sequence with 90% identity to SEQ ID NO: 17.

12. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Levi et al.

Levi et al teach a sequence (a 10 mer) that has 80% identity to SEQ ID NO 19. The intended use for the polynucleic acid of claim 13 is given no patentable weight. Further, it is noted that such sequences possess enough identity to the disclosed SEQ ID NO 19 so as to be able to hybridize to the complement of SEQ ID NO 19 (no specific conditions recited). The exact sequence of SEQ ID NO 19 was not disclosed in EP 97202303. Further, the EP 97202303 document does not teach or suggest truncating the disclosed sequences to arrive at the sequence of SEQ ID NO 19, therefore claims reciting such have an effective filing date of June 2, 1998.

The response traverses the rejection. The response asserts that applicant disagrees with the Examiner's assertion that the first priority document of the current application, EP 97202808, does not provide sufficient basis for claims pending. This is noted, however as the response provides reasoning as to where the specific sequence of SEQ ID NO: 19 finds support in the EP 97202808 patent, the examiner is unable to address the traversal further.

Further, the sequence of Levi is a 10 mer and thus meets the length limitation of claim 22. SEQ ID NO: 19 is a 27 mer. A sequence possessing 90% identity can encompass at least 2 mismatches. Since the claim does not stipulate where these mismatches are and does not limit the identity of the mismatches, the sequence of Levi represents a 'fragment of about 5-50 nucleotides long' of a sequence with 90% identity to SEQ ID NO: 19.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

13. Claims 6, and 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is dependent on itself, recites a method, and only discloses products with no positive process steps

Claims 21 and 22 are indefinite in the recitation of "fragment of 5-50 nucleotides" because SEQ ID NOS 17 and 19 are 27 mers, therefore a 28 mer sequence could not come from within SEQ ID NO: 17 or 19. Therefore, it is unclear if the fragment recitation is drawn to only sequences that come from within SEQ ID NO: 17 or 19, or if the claimed nucleic acids

encompass sequences partially from within SEQ ID NOS 17 or 19 which can contain sequences on either side wherein the nucleic acid is up to 50 nucleotides in length.

Claim Rejections - 35 USC § 102

14. Claims 12 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Harvey et al (referred to as Harvey; Journal of Biological Chemistry, vol. 246, pp 4523-4530; 1971).

Harvey teaches the nucleic acid sequence TTTTTTT. Such is a 7 mer, and thus meets the length limitation of claim 22. It is identical to positions 215-221 of SEQ ID NO: 1 and is thus a fragment of SEQ ID NO: 1. It would be capable of binding to genomic DNA comprising SEQ ID NO: 1 (would bind to complement) and could be used for HA-1 typing. It is further noted that Harvey teaches $d(T)_{12}$ which is identical in all but one position to positions 211-222 of SEQ ID NO: 1. This sequence taught by Harvey is a 12mer and thus meets the length limitation of claim 22. A sequence possessing 90% identity can encompass at least 37 mismatches with SEQ ID NO: 1. Since the claim does not stipulate where these mismatches are and does not limit the identity of the mismatches, the sequence of Harvey represents a 'fragment of about 5-50 nucleotides long' of a sequence with 90% identity to SEQ ID NO: 1.

With regard to claims 21 and 22, the claim is unclear as to whether the fragments are drawn to 5-50mers from the disclosed sequence (which would not make sense with regard to SEQ ID NO: 17 and 19 because they are 27 mers and thus a 28 mer could not come from "within" SEQ ID NO: 17 or 19). Therefore the claims have been broadly interpreted to encompass that the fragments are sequences that can partially come from SEQ ID NO: 17 and 19, and contain sequences on either side. The claim does not make clear, however, how much of a fragment of SEQ ID NO: 17 or 19 is encompassed by this recitation. As such, a fragment

could have as little as 2 nucleotides in common with the recited SEQ ID NOS: (for instance, both SEQ ID NO: 17 and 19 contain a TT at positions 20-21) and also contain sequences on either side. As such, the sequence of Harvey anticipates the claimed recitation.

15. Claims 11, 12 and 15 are rejected under 35 U.S.C. 102(a) and 35 U.S.C. 102(e) as being anticipated by Wang et al (referred to as Wang; US Patent 5,567,583).

Wang teaches a nucleic acid sequence (SEQ ID NO: 8 of Wang) which is an 11 mer. This sequence is completely complementary to positions 12 to 22 of both SEQ ID NOS: 17 and 19 and thus would be capable of specifically binding to SEQ ID NOS 17 and 19 under stringent conditions. The recitation of "specifically binds" in the claim is not sufficient to distinguish the claimed sequences from the sequence of Wang because the recitation does not exclude binding to other sequences as well. The specification does not define the phrase "specifically binds". The specification's definition for "specifically hybridize" (page 14) is not sufficient to distinguish the claimed sequences from the sequence of Wang because the definition is dependent on the identity of the nucleic acids in a sample, which is not defined by the specification. With regard to claim 15, Wang further teaches packaging the sequence in kit format (see col. 3, lines 24-30) with a polymerase. Further, with regard to claim 12, the recitation of "probe" does not distinguish the nucleic acid structurally over the sequence of Wang.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Claims 2-10, 14, 16, 17, 23, and 24 are free of the prior art. Claims 11, 12, 15, and 20-22 would overcome the rejections under 35 USC 112, first paragraph and 35 USC 102 if amended to "an isolated nucleic acid molecule consisting of the sequence of SEQ ID NO: 1 or SEQ ID NO: 17, or SEQ ID NO: 19 or the complement of SEQ ID NO: 1, SEQ ID NO: 17 or SEQ ID NO: 19" or a kit comprising an isolated nucleic acid consisting of the sequence of SEQ ID NO: 1 or SEQ ID NO: 17, or SEQ ID NO: 19 or the complement of SEQ ID NO: 1, SEQ ID NO: 17 or SEQ ID NO: 19.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (703) 308-

6565. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

Note: The examiner's name has changed from Jehanne Souaya to Jehanne Sitton. All future correspondence to the examiner should reflect the change in name. It is also noted that after January 12, 2004, the examiner will be located at the new USPTO campus and will be reachable at telephone number (571) 272-0752.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Sitton

Jehanne (Souaya) Sitton
Primary Examiner
Art Unit 1634
12/11/03